IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

RYAN HYSELL and CRYSTAL HYSELL, on behalf of their daughter, A.H., a minor,

Plaintiffs,

 $\mathbf{v}_{\boldsymbol{\cdot}}$

Case No. 5:18-cv-01375

RALEIGH GENERAL HOSPITAL, and THE UNITED STATES OF AMERICA.

Defendants.

DEFENDANT, RALEIGH GENERAL HOSPITAL'S, REPLY TO PLAINTIFFS' RESPONSE TO ITS MOTION FOR NEW TRIAL PURSUANT TO RULE 59 OF THE FED. R. CIV. P.

Defendant, Raleigh General Hospital (RGH), by counsel, D.C. Offutt, Jr., Jody Simmons, and the law firm of Offutt Nord, PLLC, and C.J. Gideon, Bryan Essary and the law firm of Gideon, Essary, Tardio & Carter, PLC, hereby respectfully submits this Reply to Plaintiffs' Response to Its Motion for New Trial Pursuant to Rule 59 of the Fed. R. Civ. P.

Introduction

Plaintiffs filed a collective response [Doc. 326] to RGH's Motion for Judgment as a Matter of Law Pursuant to Rule 50(a) [Docs. 306 and 307], Motion for Judgment as a Matter of Law Pursuant to Rule 50(b) [Docs. 309 and 310], and RGH's Motion for New Trial Pursuant to Rule 59 [Docs 311 and 312]. This reply addresses the response to the Rule 59 motion. A separate reply will be filed to address the response to the Rule 50 motions.

<u>Argument</u>

The jury verdict must be overturned because it is against the clear weight of the evidence and upholding it will result in a miscarriage of justice. Throughout the trial and in their response to this motion, Plaintiffs used the word "hypoxia" very loosely in an attempt to confuse the jury and the Court. They argue that because various experts agreed that "hypoxia" could have caused Aubrie's injuries, a reasonable jury could conclude that Aubrie suffered a hypoxic ischemic event during the labor and delivery period. However, the timing of the brain damaging hypoxia is the key issue in this case. In order for the Plaintiffs to prevail at trial, they had to prove to a reasonable degree of medical probability that the brain damaging hypoxic injury occurred around the time of birth, which they failed to do.

Every single expert who testified at trial regarding the timing of Aubrie's injury, with the exception of Dr. O'Meara,¹ testified that it occurred in utero, many weeks before the labor and delivery period. Although Dr. Barakos testified that it could have occurred anywhere from 24 weeks gestation to 2 years of age, he did not offer the opinion that the injury actually occurred during labor and delivery.² On the other hand, nine expert witnesses testified that Aubrie did not suffer a hypoxic brain injury during labor and delivery or her hospitalization at RGH based upon widely accepted scientific evidence.

It is undisputed that Aubrie's MRIs show periventricular leukomalacia

¹ Dr. O'Meara's testimony should be stricken for the reasons set forth in Defendant's Motion for New Trial.

² Jerome Barakos, M.D., Trial Transcript, Vol. V., 1173, 2-4.

("PVL"), which is an injury to the white matter of the premature brain.³ It is also undisputed that permanent brain damage that occurs during the labor and delivery period also causes damage to the gray matter in a term infant's brain.⁴ Every medical expert who testified at trial regarding the MRI findings agreed that there was absolutely no damage to the gray matter of Aubrie's brain on either MRI.⁵ Although the Plaintiffs argue that Dr. Sze contradicted himself at trial, his testimony is being completely misconstrued and taken out of context. Dr. Sze was very clear that just because PVL is seen on an MRI of a child who was born at full term, it does not mean that the injury occurred at birth.⁶ He further testified that when full term infants have an MRI which shows white matter brain injury, the injury may not be identified earlier during the gestation period because it is hard to diagnose in utero.⁷ Dr. Sze also testified that PVL most commonly occurs in infants 32 weeks gestation or less, and that he believes that Aubrie's PVL injury most likely occurred prior to 32 weeks gestation.⁸

Every other expert who interpreted the MRIs agreed with Dr. Sze that Aubrie's brain injury occurred during the prenatal period. Dr. Trock testified that Aubrie's MRIs demonstrate PVL, which occurs between 28 and 36 weeks gestation.⁹ Dr. Trock further testified that this type of injury cannot occur after 36 weeks gestation;¹⁰

³ Thomas Rugino, M.D., Trial Transcript, Vol. V, 1029, 20-24.

⁴ Gary Trock, M.D., Trial Transcript, Vol. V, 971, 7-23.; Joshua Shimony, M.D., Vol. VI, 1261, 12-20.

⁵ Gary Trock, M.D., Trial Transcript, Vol. V, 971, 7-23; Joshua Shimony, M.D., Vol. VI, 1262, 10-12; Jerome Barakos, M.D., Trial Transcript, Vol. V, 1191, 23 to 1192, 2.

⁶ Gordon Sze, M.D., Trial Transcript, Vol. VII, 1769, 13-14.

⁷ *Id.* at 1773, 13-19.

⁸ Id. At 1743, 22 to 1744, 2; 1476, 15-17.

⁹ Gary Trock, M.D., Trial Transcript, Vol. V, 972, 11.

¹⁰ *Id.* at 973, 5.

therefore, Aubrie's brain injury occurred at least five weeks prior to the labor and delivery admission. 11 Dr. Shimony agreed that Aubrie had PVL on her MRI scans and he explained to the jury that this pattern of injury typically occurs toward the end of the second trimester and beginning of the third trimester, which is when the injury occurred to Aubrie's brain. 12 He further testified that if Aubrie had a hypoxic brain injury during the delivery process that the gray matter of her brain would be effected, which is not present.¹³ Dr. Gropman also testified that Aubrie's MRIs do not support the Plaintiffs' theory that the injury to Aubrie's brain occurred during the labor and delivery period. 14 Additionally, she testified that the MRI images show abnormal brain development that began in utero, long before Ms. Hysell presented to RGH.¹⁵ She explained that if there was a hypoxic injury at birth, signature fingerprints of the injury would be seen on MRI and these findings are absent in Aubrey's case. ¹⁶ Finally, Dr. Scher testified that Aubrie's MRIs show that she had a developmental problem that began in the first half of the pregnancy, 17 and that the events at the time of her birth through her discharge had no role in causing her brain injury.¹⁸

Out of the six experts who testified regarding the interpretation of Aubrie's MRIs, five of them agreed that Aubrie's injury demonstrated on MRI occurred many

¹¹ *Id.* at 973, 10-13.

¹² Joshua Shimony, M.D., Trial Transcript, Vol. VI, 1257, 3-22; 1285, 5-8.

¹³ *Id.* at 1258, 18-25 to 1262, 12.

¹⁴ Andrea Gropman, M.D., Trial Transcript, Vol. IV, 728, 18-21.

¹⁵ *Id.* at 730, 18 to 731, 1.

¹⁶ *Id.* at 773, 6-12.

¹⁷ Mark Scher, M.D., Trial Transcript, Vol. VIII, 1792, 24 to 1793, 2.

¹⁸ *Id.* at 1795, 4-13.

weeks before labor and delivery. Even the Plaintiffs' neuroradiology expert, Dr. Barakos, does not dispute that the injury could have occurred as early as 26 weeks gestation. Accordingly, the weight of the evidence presented at trial clearly proved the injury to Aubrie's brain occurred many weeks prior to her birth based upon her MRIs.

Furthermore, the unrefuted, published, and peer reviewed information in Neonatal Encephalopathy and Neurologic Outcome establishes that neonatal encephalopathy must be present to attribute cerebral palsy to hypoxic ischemia that occurs during labor and delivery. This authoritative text jointly published in 2014 by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology confirms an Apgar score of 7, or better, at 5 minutes of life, leads to the widely accepted conclusion that hypoxia is not a probable cause of later diagnosed cerebral palsy.²⁰ Aubrie's APGAR scores were a 7 and 8, which are completely normal. It is also undisputed that Aubrie did not have neonatal encephalopathy at birth. Dr. Graham testified that Aubrie's APGAR scores are normal and do not suggest a hypoxic injury.²¹ He further testified that there is no evidence of an oxygen deficit at birth.²² Likewise he testified that there is no evidence of a hypoxic ischemic injury at birth or neonatal encephalopathy.²³ Finally, he concluded that Aubrie did not experience neonatal encephalopathy and that her problems are not due to a lack

¹⁹ Jerome Barakos, M.D., Trial Transcript, Vol. V., 1173, 2-4

²⁰ Ernest Graham, M.D., Trial Transcript, Vol. IV, 952, 4-15.

²¹ *Id.* at 940, 10-21; 941, 17-20.

²² *Id.* at 944, 9-16.

 $^{^{23}}$ *Id*.

of oxygen around the time of birth.²⁴

In their response to the instant motion, the Plaintiffs misconstrue Dr. Graham's testimony by failing to cite the entire statements that he made at trial. For example, the Plaintiffs argue that he testified that not all babies who have hypoxic brain injuries have organ failure or seizures, which is true, but Dr. Graham went on to testify that these babies also do not have APGAR scores of a 7 and 8 and go home a day later.²⁵ He further testified that hypoxic brain injured babies are very flaccid and hypotonic and "you would never send a baby with a hypoxic brain injury home in a day because they are too sick."²⁶ This was not the case with Aubrie.

Dr. Gropman further testified that if brain damaging hypoxia occurs at birth, the baby will demonstrate neonatal encephalopathy which was not present here.²⁷ Dr. Trock testified that neonatal encephalopathy must be present if a brain injury at the time of birth occurred, which Aubrie did not have.²⁸ Dr. Giannone testified that children who suffer brain damage due to a lack of oxygen during labor and delivery will demonstrate neonatal encephalopathy²⁹, which Aubrie did not have.³⁰ Dr. Scher also testified that Aubrie did not have neonatal encephalopathy.³¹ Dr. Landon, testified that there was no hypoxic injury based on all the circumstances including Aubrie's condition, lack of acidosis, and lack of any real neurological

²⁴ *Id*. At 953, 10-14.

²⁵ Ernest Graham, M.D., Trial Transcript, Vol. IV, 1099, 24 to 1100, 1.

²⁶ *Id.* at 1100, 9-14.

 $^{^{\}rm 27}$ Andrea Gropman, M.D., Trial Transcript, Vol. IV, 774, 4 to 775, 4.

²⁸ Gary Trock, M.D., Trial Transcript, Vol. V, 973, 14 to 975, 4.

²⁹ Peter Giannone, M.D., Trial Transcript, Vol. VII, 1550, 13-17.

³⁰ *Id.* at 1555, 19-23 and 1559, 7-19.

³¹ Mark Scher, M.D., Trial Transcript, Vol. VIII, 1796, 1-19.

symptomatology.³² Finally, Dr. Bedrick testified that if Aubrie had suffered such an injury, she would have shown signs of neonatal encephalopathy, which was not present.³³

The Plaintiffs produced no evidence at trial that Aubrie exhibited any signs of neonatal encephalopathy, which must be present if she truly suffered a hypoxic brain injury during labor and delivery. Both the MRI evidence and the lack of neonatal encephalopathy support that Aubrie's injury did not occur at the time of birth; therefore, a new trial must be granted.

The Plaintiffs also falsely argue that the Defendants created the "microcephalic argument" for trial. The opposite is true. The Plaintiffs desperately tried to prove that Aubrie was not microcephalic at birth, when she was in fact with a head circumference of 31.9 cm.³⁴ Dr. O'Meara is the only expert who opined that Aubrie was not microcephalic at birth,³⁵ which is completely contrary to scientific principals and the rest of the evidence presented at trial. She offered no evidence to support her opinion that Aubrie did not have microcephaly at the time of birth. Dr. Arthur, a treating child neurologist, testified that Aubrie was "definitely" microcephalic at birth.³⁶ The Plaintiffs' own experts, Dr. Rugino and Dr. Barakos, agreed that a head circumference at birth of 31.9 cm is microcephalic.³⁷ Dr. Gropman, Dr. Trock, Dr. Giannone, Dr. Bedrick, Dr. Scher, Dr. Graham, and Dr.

³² Mark Landon, M.D., Trial Transcript, Vol. IX, 1918, 7-18.

³³ Alan Bedrick, M.D., Trial Transcript, Vol. IX, 1844, 1-14.

³⁴ Heather Buchanan, R.N., Trial Transcript, Vol. I, 227, 1-11.

³⁵ A. M. Igbal O'Meara, M.D., Trial Transcript, Vol. III, 591, 23-24.

³⁶ Todd Arthur, M.D., Trial Transcript, Vol. II, 454, 20

 $^{^{\}rm 37}$ Thomas Rugino, M.D., Trial Transcript, Vol. V., 1058, 9-21; and Jerome Barakos, M.D., Trial Transcript, Vol. V, 1185, 6-15..

Shimony all also testified that Aubrie was microcephalic at birth, and that a child injured by hypoxia at birth would not be microcephalic at birth.³⁸ Instead, Dr. Graham explained that microcephaly establishes a "long ongoing problem with this baby"³⁹ well before birth. The overwhelming weight of the evidence supports that microcephaly at birth cannot occur due to hypoxia during the labor and delivery period, and confirmed Aubrie's brain injury did not occur at or around the time of delivery.

Finally, the Plaintiffs' Life Care Plan and related evidence was inappropriately admitted during trial because Dr. Rugino failed to provide the necessary evidentiary support for it. Ms. Lampton's trial testimony confirmed that Dr. Rugino told her to "include all of those items" listed in his *initial* report without any offsets, deductions, or omissions related to autism. ⁴⁰ Her understanding, "from my conversation with Dr. Rugino, is that everything in [the Trial Life Care Plan] is based upon her current condition" without any separation of autism versus cerebral palsy versus some other developmental delays⁴¹ – "he said it did not need to be separated out." ⁴²

³⁸ Andrea Gropman, M.D., Trial Transcript, Vol. IV, 773, 21-24; 774, 12-15; Joshua Shimony, M.D. Trial Transcript, Vol. VI, 1263, 9-12; Peter Giannone, M.D., Trial Transcript, Vol. VII, 1542, 21 to 1543, 4; 1543, 14-18; 1546, 22 to 1547, 12; Mark Scher, M.D., Trial Transcript, Vol. VIII, 1803, 2-5. As a matter of fact, Dr. Scher used growth charts from the CDC and W.H.O., to confirm the measurements "were all substantially in the second percentile." Id. at 1813, 18 to 1814, 1; Alan Bedrick, M.D. Trial Transcript, Vol. IX, 1846, 9 to 1847, 4; Gary Trock, M.D., Trial Transcript, Vol. V, 996, 23 to 997, 11; Ernest Graham, M.D., Trial Transcript, Vol. V, 927, 15-17.

³⁹ Ernest Graham, M.D., Trial Transcript, Vol. V, 927, 15-17.

⁴⁰ Laura Lampton, R.N., Trial Transcript Vol. IV, 848, 5-20.

⁴¹ *Id.* at 862, 4-14.

⁴² Id. at 834, 3-11.

Consequently, the Trial Life Care Plan was presented to this Court and to the Jury with "no offsets whatsoever" for autism.⁴³

Dr. Rugino finished testifying after Ms. Lampton, and he testified that after he learned of Aubrie's genetic testing performed in February 2020⁴⁴ (and after the First Life Care Plan had been prepared in September 2019), that he had some sort of previously undisclosed "line-by-line" review with Ms. Lampton and supposedly "outlined what has to be taken out due to consideration of the fact that [Aubrie] would have been born with autism." Yet, nothing was removed and The Trial Life Care Plan failed to accurately reflect Aubrie's future needs. Accordingly, The Trial Life Care Plan, Ms. Lampton's testimony, and the resultant calculations of Mr. Staller failed to accurately reflect Dr. Rugino's supposedly supporting opinion and this evidence should not have been considered by the jury. As a result, the Defendant is entitled to a new trial.

Conclusion

The clear weight of the evidence shows that Aubrie did not suffer a hypoxic brain injury at or around the time of her birth. Her MRIs show that the injury occurred in utero many weeks prior to her birth. Likewise, Aubrie's APGAR scores were perfectly normal, and she did not demonstrate neonatal encephalopathy which would be present in the event that she suffered a hypoxic brain injury at birth. Additionally, her head was microcephalic at birth which demonstrates that her injury

⁴³ Id. at 838, 24 to 839, 9.

⁴⁴ Thomas Rugino, M.D., Trial Transcript Vol. V, 1049, 1-6.

⁴⁵ Id. at 1049, 12-21.

occurred long before her birth which precluded her head from growing properly. Accordingly, the jury's verdict is against the clear weight of the evidence and a new trial is warranted. In addition, the admission of The Trial Life Care Plan, as well as the related testimony and Mr. Staller's calculations, resulted in the jury being presented with inappropriate and unsupported medical and other expenses, which entitles the Defendant to a new trial. Upholding the verdict would constitute a miscarriage of justice.

WHEREFORE, Raleigh General Hospital respectfully requests that this Court enter an Order granting its motion for a new trial, and for any additional relief that this Court deems just.

RALEIGH GENERAL HOSPITAL,

By Counsel

/s/D.C. Offutt, Jr.

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CERTIFICATE OF SERVICE

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The undersigned, counsel for Defendant, Raleigh General Hospital, hereby certifies that a true and exact copy of the foregoing, "Defendant, Raleigh General Hospital's, Reply to Plaintiffs' Response to Its Motion for New Trial Pursuant to Rule 59 of the Fed. R. Civ. P.," has been served upon counsel of record via electronic filing, this 6th day of August, 2021:

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